OSMOLARITY SYSTEM **USER MANUAL**

MEDICAL DESIGN EXCELLENCE AWARDS®
2009 WINNER

TearLab™
Osmolarity System

OSMOLARITY SYSTEM ⊕ CONTENTS

INCLUDED CONTENT:

TEARLAB READER

PEN

ELECTRONIC CHECK CARDS

- TearLab Reader
- (2) TearLab individually boxed Pens with magnetic cardboard sleeves, Instructions for Use, and a set of adhesive identification labels
- Set of (2) Electronic Check Cards with Instructions for Use
- TearLab User Manual
- TearLab Quick Reference Guides
- Power Supply
- Power Cord(s)

SOLD SEPARATELY:

OSMOLARITY TEST CARDS

OSMOLARITY CONTROL SOLUTIONS

TearLab™

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OSMOLARITY SYSTEM ⊕ PRODUCT OVERVIEW

The TearLab Osmolarity System is a tear fluid collection and testing device for the quantitative measurement of osmolarity (concentration of dissolved, active particles in solution) of human tears in normal and Dry Eye Disease patients. TearLab is for professional *in vitro* diagnostic use only.

Tears fulfill an essential role in maintaining ocular surface integrity, protecting against microbial challenge, and preserving visual acuity. These functions, in turn, are critically dependent upon the composition and stability of the tear film structure. Disruption, deficiency, or absence of the tear film can severely impact the eye. Associated disorders can lead to desiccation of the corneal epithelium, ulceration and perforation of the cornea, an increased incidence of infectious disease, and other clinical conditions.[1]

Hyperosmolarity has been described in the literature as a primary marker of tear film integrity.[2] When either the quantity or quality of secreted tears is compromised (known as aqueous deficient or evaporative Dry Eye Disease), increased rates of evaporation lead to a concentrated tear film (increased osmolarity) that places stress on the corneal epithelium and conjunctiva.

The TearLab Osmolarity Test Card, in conjunction with the TearLab Osmolarity System, provides a quick and simple method for determining tear osmolarity using nanoliter (nL) volumes of tear fluid collected directly from the eyelid margin. To perform a test, attach a new Test Card onto the Pen and touch the tip of the Pen to the tear fluid meniscus located above the lower eyelid. After a successful collection, dock the Pen into the Reader, which will display a quantitative tear osmolarity test result on the liquid crystal display (LCD). The TearLab Osmolarity System simplifies the tear-collection process by eliminating the need to transfer tear fluid samples and reducing the risk of evaporation.

PRINCIPLES OF THE PROCEDURE

The TearLab Osmolarity Test utilizes a temperature-corrected impedance measurement to provide an indirect assessment of osmolarity.[3] After applying a lot-specific calibration curve, osmolarity is calculated and displayed as a quantitative numerical value.

OSMOLARITY SYSTEM ⊕ SYSTEM COMPONENTS

TEARLAB OSMOLARITY SYSTEM READER

The Reader is a portable countertop unit that calculates and displays the osmolarity test result. The Reader has an LCD screen, a keypad, and an external AC power supply. Left and right cradles allow two Pens to dock into the Reader. When Pens are docked, the Reader automatically converts the tear fluid sample data into an osmolarity measurement and displays the reading on the LCD.

TEARLAB OSMOLARITY SYSTEM PEN

The Pen is designed to hold the Test Card and facilitate safe, simple tear fluid collection. The Pen electronics confirm the proper attachment of the Test Card onto the Pen, detect the presence of tear fluid in the Test Card, and signal when a tear fluid sample has been successfully collected. Powered by a permanent rechargeable battery, the Pen provides a mechanical/electrical interface to convey data to the Reader automatically when docked. Each TearLab Osmolarity System includes two Pens to allow sequential tear fluid sample collection from multiple patients or from the left and right eyes of a single patient.

TEARLAB OSMOLARITY TEST CARD

Each Test Card is a single-use, individually packaged, nonsterile, polycarbonate microchip containing (a) microfluidic channel to collect 50 nanoliters (nL) tear fluid by passive capillary action and (b) gold electrodes embedded in the polycarbonate to enable onboard measurement of tear osmolarity. Test Cards are clinically hygienic and have a protective cover that should be removed only after the Test Card has been successfully attached onto the Pen and immediately prior to tear collection. Each Test Card is imprinted with a code that must be entered onto the Reader at time of testing. Designed to work in conjunction with the TearLab Pen, the Test Card does not contain chemicals or reagents, and collects tear fluid in less than one second. Please note that TearLab Osmolarity Test Cards are not included with the TearLab Osmolarity System and must be purchased separately.

TEARLAB ELECTRONIC CHECK CARDS

Two identical, blue reusable Electronic Check Cards are provided as a procedural quality control to confirm the function and calibration of the TearLab Osmolarity System within manufacturer specifications. The Electronic Check Cards can be used simultaneously for quality control testing, one with each Pen. The Electronic Check Cards can be used to verify the function of the TearLab if it is mishandled or the Pens are dropped. Tear fluid samples cannot be collected with the Electronic Check Cards.

TEARLAB CONTROL SOLUTIONS

TearLab Osmolarity Control Solution is a quality control material used for verifying the quantitative performance of TearLab Osmolarity Test Cards when used with the TearLab Osmolarity System. Routine use of TearLab Osmolarity Control Solution enables laboratories to monitor day-to-day test variation, lot-to-lot test kit performance and to assist in operator training. These controls can also be used to troubleshoot invalid results and to identify increases in random or systemic error.

OSMOLARITY SYSTEM ⊕ INSTALLATION

A Reader, two Pens, a power supply, power cord, and Electronic Check Cards are delivered together with a User Manual and Quick Reference Guides. Open the carton on a stable surface, remove the components, and set them on a flat surface with at least two inches of space around the Reader. The Reader and Pens should not be used in direct sunlight and should be at ambient temperature (15-30°C/59-86°F) before use. After switching the Reader ON, a 25-minute warm-up before use is required. The Reader will indicate when it is ready for use.

1. Each Pen comes with a set of identification labels that can be affixed to the back of the Pen to distinguish one Pen from the other. Affix labels to the back of each Pen, if desired. Each Pen is also supplied with a reusable magnetic cardboard sleeve for long-term storage. DO NOT DISCARD. (See "Long-Term Pen Storage" section on page 3 of this manual.)

2. Insert each Pen into a cradle. The Reader has two cradles to allow simultaneous docking of both Pens. Either Pen will function in either cradle.

3. Select the power cord that corresponds to your local electrical outlet configuration. Connect the power cord to the power supply, plug the power cord into an electrical outlet, and connect the power supply to the back of the Reader. Locate the switch on the back of the Reader and set to the ON ⊙ position.

WARNING: *Modification of this equipment is not recommended and will nullify the manufacturer's warranty.*

INITIAL SETUP AND MENU NAVIGATION

- Upon first use, press the MENU Key ☰ once to enter the Menu Mode and setup screen.
- Press the RECALL Key ⮌ below the up and down arrows to scroll.
- Press the OK Key OK to choose a menu item.
- Press the MENU Key ☰ to return to the main screen.
- When in Test Mode, press the RECALL Key ⮌ to display the previous test result.

RECALL KEYS AND TEST MEMORY

There are two RECALL Keys corresponding to the left and right cradles. RECALL Keys are used to view the previous test result.

To recall the previous test result, press and hold the RECALL Key. The previous test result will be displayed on a dark background to distinguish it from the current test result. Release the RECALL Key and the LCD will revert to the active screen, displaying the current test result or operation screen. Only the last test result will be held in memory, and it will remain in memory until the Reader is turned OFF. The RECALL Keys also function as UP and DOWN when entering the code or navigating the menu.

When turned ON, the Reader LCD will display "Ready," indicating that testing may be performed. The LCD is split into left and right sides, corresponding to the left and right docking cradles.

OSMOLARITY SYSTEM PENS

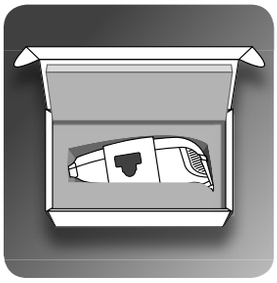
TEARLAB PENS

Each Pen contains a permanent rechargeable battery. Pens should be docked in the Reader and allowed to charge for 20 minutes before initial use. The Pen battery automatically recharges when the Pen is docked in the Reader and the power is switched ON. It is recommended that the Reader power remain ON for continuous Pen battery charging. A battery icon is located in the left and right corners of the LCD. A flashing battery icon indicates that the battery is charging. If not flashing, the battery is fully charged. Pen batteries will not overcharge.

WARNING: *Only collect tears if the green light is on. NEVER collect tears when the green light is off. If a Test Card is attached and there is no beep and no green light from the Pen, DO NOT collect tears.*

LOW BATTERY WARNING

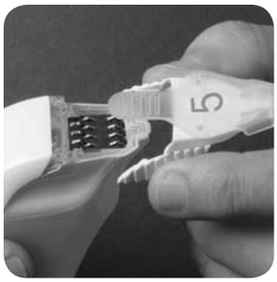
When a Pen with low battery power is removed from the Reader, the Reader will emit two informational beeps and the "BAT LOW" message will appear on the LCD. Do not perform testing. Dock the Pen into the Reader to charge the battery. When "BAT LOW" changes to "Ready," the Pen is ready to perform a test.



LONG-TERM PEN STORAGE *Please retain Pen box and Magnetic cardboard sleeve for long-term storage.*

The Pen is packaged with a magnetic cardboard sleeve that automatically turns the Pen OFF when the Pen is properly inserted. When the magnetic cardboard sleeve is removed, the Pen automatically turns ON. The Pen will remain ON indefinitely, in either Wake or Sleep Mode. If the Pen is not used for 30 days or more, it is recommended to store the Pen in the magnetic cardboard sleeve and in its original box to turn the Pen OFF and to conserve the life of the battery. Failure to store the Pen properly may result in a battery that is completely discharged beyond its ability to recharge.

- Pen batteries are permanent and cannot be exchanged or replaced. Battery failure requires replacement of the Pen.
- The Pen battery will not overcharge.
- If the Pen has been dropped or mishandled, test with an Electronic Check Card to verify that it is functioning properly before testing patients or Control Solutions.



WAKE AND SLEEP MODES

The Pen will enter Sleep Mode when not in use and will automatically awaken when a new Test Card is attached, as indicated by the green light and the beep. The Pen will remain in Wake Mode for two minutes. If two minutes pass without tear collection, the Pen will return to Sleep Mode and the green light will turn off. To wake the Pen, remove the Test Card and reattach it onto the Pen. The green light will illuminate and the Pen will beep.

Following tear collection, a user has 40 seconds to return the Pen to the Reader before the Pen enters Sleep Mode. If the Pen enters Sleep Mode following tear collection, the data will be erased and the Test Card will not be able to be reused.

WARNING: *Pen should always be docked immediately after tear collection to avoid loss of data.*

CALIBRATION

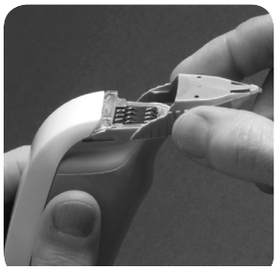
The manufacturer calibrates the TearLab Osmolarity System against a reference standard solution prepared from dried, high-purity sodium chloride traceable to the National Institute of Standards and Technology (NIST). Calibration by the user is not required.

ELECTRONIC CHECK CARD

The blue Electronic Check Card should be tested on each Pen before each day of patient testing, or if the Pen has been dropped or mishandled, to verify that the system is performing within manufactured calibration specifications. Values obtained with the Electronic Check Card should not deviate by more than +/- 3.0 mOsms/L (units of osmolarity) from the expected value.

The TearLab Osmolarity System comes with two identical blue reusable Electronic Check Cards. The Electronic Check Cards can be used simultaneously on each Pen for quality control testing.

WARNING: *Fluid samples cannot be collected with the Electronic Check Card. DO NOT try to collect tears or Control Solutions with the blue Electronic Check Card.*



TESTING THE ELECTRONIC CHECK CARD

1. Attach an Electronic Check Card onto a Pen. The green light on top of the Pen will illuminate and the Pen will beep. Wait approximately five seconds for the Pen to beep again or for the green light to turn off.

2. After the green light turns off, dock the Pen into the Reader. The LCD will display a code number. It is not necessary to enter a specific code for Electronic Check Cards. Press OK to accept any code.

3. The LCD will display a test result that should fall within the expected value range indicated in the "Instructions for Use" provided with the Electronic Check Cards.

- Remove the Pen and press the RECALL Key to confirm that the test result was properly stored in memory.
- Repeat the procedure with the other Pen.
- Record the date and the Electronic Check Card test results in a quality log.

CONTROL SOLUTIONS

Good laboratory practice suggests the use of Normal and High Osmolarity Control Solutions to ensure that the TearLab Osmolarity System is functioning properly and that the test is being performed correctly. Routine use of TearLab Osmolarity Control Solution enables laboratories to monitor day-to-day test variation, lot-to-lot test kit performance and to assist in operator training. These controls can also be used to troubleshoot invalid results and to identify increases in random or systemic error.

Only TearLab Osmolarity Control Solutions should be used with the TearLab Osmolarity System. Osmolarity Control Solutions are not included with the TearLab Osmolarity System or the TearLab Osmolarity Test Cards. Normal and High Osmolarity Control Solutions are available in single-use glass ampoules that can be purchased separately. Contact your local sales representative or TearLab Customer Support for additional information on how to order TearLab Osmolarity Control Solutions.

Please refer to the "Testing Osmolarity Controls" section on page 7 of this manual for the Osmolarity Controls testing procedure.

SAMPLE MATERIAL

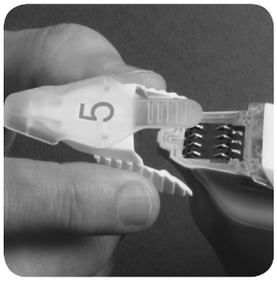
Human tear fluid samples may be used. Collect tear fluid samples directly from the eye.

- Do not collect tear fluid samples from patients who have used eye drops within two hours prior to testing.
- Do not collect tear fluid samples from patients wearing makeup on eyelids.
- Do not collect tear fluid samples within 10 minutes after removal of eye makeup.
- Do not collect or store tear fluid samples for transport or testing at a later time.
- Do not collect tear fluid after ocular surface staining.
- Do not collect tear fluid after invasive ocular diagnostic testing.
- Do not collect tear fluid within 10 minutes after a slit lamp examination.
- Do not collect tear fluid from a patient who has been crying.

WARNING: *If either the Electronic Check Card or the Normal and High Osmolarity Control Solution test results do not match the expected value range, DO NOT test patients. Contact your local sales representative or TearLab Customer Support for assistance.*

HOW TO PERFORM AN OSMOLARITY TEST

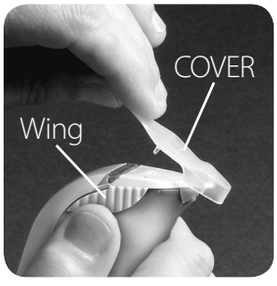
NOTE: *Use appropriate clinically hygienic methods when collecting tears. Dispose of used Test Cards in a biohazard container.*



BEFORE EACH TEST:

- Remove either Pen from the Reader. The LCD will display "Ready."

NOTE: *DO NOT collect tear samples if the Reader does not display "Ready."*



- Remove a Test Card from its package and attach it onto the Pen. The Pen will beep and the green light will illuminate when the Card is attached properly. The green light will remain on until tears are collected or the Pen times out (after two minutes).
- Remove the protective cover by holding the wings of the Test Card firmly and pulling the sheath up and off of the Test Card.

WARNING: *A Test Card without a protective cover should be considered used. DO NOT use for patient testing.*

TEAR COLLECTION PROCEDURE

NOTE: *For Osmolarity Controls, refer to "Testing Osmolarity Controls" section on page 7.*

- Seat the patient with chin tilted upward and eyes directed toward the ceiling.
- Place one hand on the face for stabilization. Do not pull the eyelid down or away from the eye.
- Position the tip of the Pen just above the lower eyelid.
- Gently lower the Pen until the bottom of the tip touches the thin line of moisture between the eyelid and eye. It is not necessary to press inward toward the eye.
- The Pen will beep and the green light will turn off after a successful tear collection.

If the Pen does not beep within seconds, withdraw it and ask the patient to blink, and then restart the process.

NOTE: *Sometimes when there is very little tear, the act of withdrawing the Pen breaks the surface tension of the tear meniscus and allows tears to enter the microfluidic channel. In this case, the Pen will beep upon withdrawal, indicating a successful tear collection.*

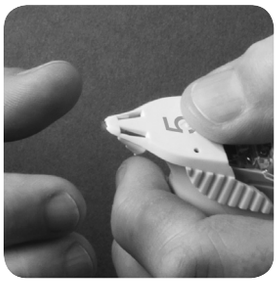
TO GET THE RESULT

- Locate the code on top of the Test Card (see example in picture).
- Dock the Pen into the Reader within 40 seconds of collecting the sample.
- Immediately press the RECALL Key ⮌ below the up or down arrows to select the Test Card code.

IMPORTANT: *If a code is not selected within eight seconds, the Reader will automatically use the default code displayed on the LCD. It is important to select the correct code to obtain an accurate osmolarity test result.*

- Press the OK Key (OK) or wait eight seconds to accept the code.
- The test result will display in a few seconds.
- Record the date and test result in the patient chart.

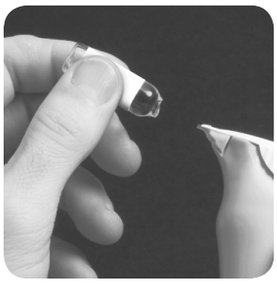
Remove the used Test Card from the Pen by pressing forward on top of the Test Card with your thumb. Do not pull from the wings. Dispose of the Test Card in a biohazard container.



TESTING OSMOLARITY CONTROLS

1. Attach a new Test Card onto a Pen (refer to "How to Perform an Osmolarity Test" section of this manual, on page 5).

- Select the Normal Osmolarity Control Solution and tap the neck of the ampoule to remove any fluid.
- Slide the blue rubber sleeve all the way down the neck of the ampoule. Snap off the top of the ampoule. Dispose of the ampoule top in a sharps container. Retain the blue rubber sleeve for future use.
- Invert the ampoule (the fluid won't spill out) and touch the tip of the Test Card to the Control Solution until the Pen beeps and the green light turns off.



2. Follow the "To Get the Result" section on page 6 in the "How to Perform an Osmolarity Test" section.
3. Confirm that the test result is within the expected value range indicated on the Control Solution Product Insert. Dispose of the ampoule in a sharps container.
4. Record date and test result in a quality log.
5. With the other Pen and a new Test Card, repeat steps 1–4 with the High Osmolarity Control Solution.

WARNING: *If either the Normal or the High Osmolarity Control Solution test results do not match the expected value range, DO NOT test patients. Contact your local sales representative or TearLab Customer Support in your area for assistance.*

OSMOLARITY SYSTEM → PERFORMANCE

PERFORMANCE CHARACTERISTICS

RESULT INTERPRETATION

TearLab test results are displayed on the LCD in mOsms/L. No calculations are required. The clinical literature often reports either osmolarity (mOsms/L) or osmolality (mOsms/kg). In tear fluid the difference between osmolarity and osmolality is insignificant, and it is common in the clinical literature to use the terms interchangeably.[4]

TearLab measurement range is linear from 275–400 mOsms/L. Test results outside this range will be reported as either "Below Range," indicating a measurement below 275 mOsms/L, or "Above Range," indicating a measurement above 400 mOsms/L. Osmolarities outside the stated range are very rare and should generally be confirmed with a subsequent test, as values outside the measurement range may be indicative of an error (e.g., user error during the test).

EXPECTED RESULTS

Reference tear osmolarity values for normal patients and patients with Dry Eye Disease:

Normal Patients: 275–316 mOsms/L (mean 302 mOsms/L)[5]
Dry Eye Disease Patients: > 316 mOsms/L (mean 327 mOsms/L)[5]

OSMOLARITY SYSTEM → SPECIFICATIONS

POWER REQUIREMENTS

Use only Power Supply Model PDM30US12 (XP Power)

POWER SUPPLY

Input voltage: 100–240 VAC
Input current: 0.6A MAX
Frequency: 47–63 Hz
Output voltage:12 VDC
Output current: 2.5A
Class II
Continuous service

SYSTEM CLASSIFICATION

Class II: powered by Class II power supply
Type B applied part
Continuous service

PEN POWER SOURCE

Input: 4.5–5.5 VDC 0.6A
Internally powered by rechargeable battery
Continuous service

ENVIRONMENTAL CONDITIONS

Transport and Storage temperature: 2–35°C/36–95°F
Transport and Storage relative humidity: 10–85% noncondensing
Transport and Storage altitude: 0–2,000 meters
Operating temperature: 15-30°C/59-86°F
Operating altitude: 0–2,000 meters
Operating relative humidity: 10–85% noncondensing

OSMOLARITY SYSTEM → HAZARDS

The TearLab Osmolarity System is designed for stability, reliability, and safety, and it has been developed, manufactured, and marketed under a quality management system certified by ISO 13485 (2003).

The TearLab Osmolarity System complies with

- WEEE Directive 2002/96/EC Waste Electrical and Electronic Equipment
- RoHS Directive 2002/95/EC Restriction of Hazardous Substances
- IEC 60601-1 Medical Electrical Equipment — General Requirements for Basic Safety and Essential Performance

The TearLab Osmolarity Test Cards do not contain reagents or chemicals.

Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

The American Academy of Ophthalmology (AAO) states: "Human tears are not considered to contain significant amounts of bloodborne pathogens and thus do not require OSHA's [Occupational Safety and Health Administration] bloodborne pathogens precautions; but exposure to human tears contaminated with blood … requires the use of bloodborne pathogens precautions."[6]

Proper handling and disposal methods of used Test Cards should be established according to relevant state and federal regulations.

TearLab is designed to collect samples of tear fluid from the eye, a nonsterile environment. The AAO has issued guidance to minimize the transmission of ocular surface infectious agents. Prevention of transmission of these pathogens requires good hygienic techniques, such as washing hands and instruments that touch the eye. Refer to the *"Maintenance"* section on page 9 of this manual for proper cleaning of the TearLab Reader and Pen. TearLab Osmolarity Test Cards are for single use, clinically hygienic, individually packaged, and contain a protective cover. Never reuse or attempt to clean a Test Card. Do not touch the Test Card tip after removal of the protective cover.

OPERATIONAL PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Use only at ambient temperature of 15–30°C/59–86°F.
- Pen timer: In order to conserve battery life, the Pen is programmed to enter Sleep Mode automatically two minutes after it powers up.
- When a Pen is not being used for 30 days or more, store it in the magnetic cardboard sleeve to conserve battery life.
- Osmolarity Test Cards are stable until the expiration date marked on the label.
- Leave Test Card in its sealed pouch until use.
- Do not remove the protective Test Card cover until attached onto a Pen. Remove the protective cover immediately prior to tear collection.
- Any Test Card that does not contain a protective cover should not be used for patient testing. A Test Card that has been dropped or contaminated without a protective cover should not be used for patient testing.
- A measurement should not be performed if a Pen that contains a Test Card with a patient sample has been dropped. Discard Test Card and test with an Electronic Check Card to verify that the Pen is performing correctly.
- Avoid touching the tip of the Test Card.
- Test Cards are for single use only. Never reuse or try to clean a Test Card.
- Dock the Pen into the Reader within 40 seconds of collecting a sample or the Pen will time out (T/O). The Pen will emit a series of reminder beeps approximately 30 seconds after tear collection to prompt immediate docking. A Pen docked into the Reader after 40 seconds will display a "Pen T/O" error message, data will be lost, and the test will be invalid.
- Test Card should not be removed after tear collection or prior to docking, or data will be lost.
- Tear collection should not be attempted if the green light on the Pen is not illuminated. The green light will not illuminate if battery power is low or the Test Card is used.
- Do not remove a Test Card from the Pen after tear collection until a measurement has been displayed. Removing a Test Card from the Pen prior to docking will clear the Pen's memory and data will be lost. The Pen will not recognize a fluid-filled Test Card if it is removed and reattached onto the Pen.
- Refer to the "Sample Material" section on page 5 and to the "How to Perform an Osmolarity Test" section on page 5 of this manual for tear fluid sample collection guidelines.
- Prior to use, inspect the Reader, Pen, and Test Card for physical damage. If anything is damaged, do not perform testing until the System performance has been verified with both the Electronic Check Cards and Osmolarity Control Solutions.

The TearLab Osmolarity System is designed to work without direct service or preventive maintenance. If quality checks fail, contact TearLab Customer Support.

The TearLab Reader and Pens can be cleaned with a damp cloth or alcohol wipe as required. When cleaning, it is important to keep the electronic contacts of the Pen and Reader dry. The electronic contacts and docking port should also be kept free of dust and dirt. Pen batteries cannot be replaced. If the Pen battery fails to recharge, contact your sales representative or TearLab Customer Support to purchase a replacement Pen. Cleaning fluids should never be used on the Test Cards.

TECHNICAL SERVICE

Contact your sales representative or TearLab Customer Support. See back cover for contact information.

REPLACEMENT PARTS

To order replacement parts, contact your local sales representative or TearLab Customer Support in your area for assistance.

PROBLEM	EXPLANATION	ACTION
Test Card is attached, green light does not illuminate, and Pen does not beep.	A. Test Card is not properly attached. B. Test Card is used. C. Pen battery is low. D. Pen electrical contacts are worn.	1. Remove Test Card and reattach if protective cover is still on. NEVER use a Test Card that does not have a protective cover. 2. Dock Pen into Reader to assess battery charge level. 3. Use the Electronic Check Card to confirm Pen function. 4. Try a new Test Card. 5. Contact TearLab Customer Support.
Pen begins beeping approximately 30 seconds after tear collection.	Pen will time out in 10 seconds.	Immediately dock the Pen into the Reader. Pen must always be docked within 40 seconds of tear collection.
Pen's green light turns off with an unused Test Card attached prior to tear collection.	1. Two minutes have passed since attachment of Test Card and Pen has entered Sleep Mode. 2. Pen battery is too low for tear collection.	1. Remove unused Test Card and reattach onto Pen. Proceed with tear collection. 2. Dock the Pen to allow battery to recharge. Reader LCD will indicate battery charging status.
Electronic Check Card does not fall within the expected value range.	The TearLab Osmolarity System does not meet manufacturer specifications.	Retest using the second Electronic Check Card. If result does not fall within the expected value range, contact TearLab Customer Support.
Osmolarity Control Solution results do not fall within the expected value range.	Either Test Cards or TearLab Osmolarity System do not meet manufacturer specifications.	1. Check the expiration date of the Test Card and Osmolarity Controls. 2. Test with the Electronic Check Card. A. If results are out of range, contact TearLab Customer Support. B. If results are in range, retest Osmolarity Controls. If results are still out of range, contact TearLab Customer Support. 3. Do not perform patient testing until Osmolarity Control results are within the expected value range.
When Pen is removed from Reader, Pen beeps twice and LCD displays "BAT LOW."	Pen battery is low and testing cannot proceed.	Dock Pen into Reader to recharge battery.
Reader LCD displays "Used T/C."	Test Card has already been used. Test Cards are for single use. Pen will not accept a Test Card that has been used previously to collect tear fluid samples.	Remove the Test Card and dispose in a biohazard container. Attach a new Test Card and proceed with testing. If necessary, the last test can be recalled by pressing and holding the RECALL Key.
Reader LCD displays "Pen T/O."	Pen was not docked into Reader within 40 seconds of tear collection. Data is lost.	Retest patient with a new Test Card. Dock Pen into Reader within 40 seconds of tear collection.
Reader LCD displays "Above Range."	Test result was above 400 mOsms/L.	Verify function with quality control procedures. Retest patient, as values outside the measurement range may be indicative of an error. Once confirmed, record patient result as "Above 400 mOsms/L."

PROBLEM	EXPLANATION	ACTION
Reader LCD displays "Below Range."	Test result was below 275 mOsms/L.	Verify function with quality control procedures. Retest patient, as values outside the measurement range may be indicative of an error. Once confirmed, record patient result as "Below 275 mOsms/L."
Need to confirm which Test Card code was entered onto Reader after an osmolarity test was performed.	Not sure if correct Test Card code was entered onto Reader during test. Osmolarity test result may be inaccurate.	Using either Pen, test with an Electronic Check Card in the same docking port as the test in question. The Test Card code that is displayed on the Reader LCD will be the same code as the last test performed. Verify if this Test Card code matches the code for the test in question. If it does not match, disregard the osmolarity test result.
Reader fails to detect a docked Pen.	Pen or Reader electrical contact failure.	Dock Pen, charge batteries, and retest with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.
Reader LCD displays "E51."	Pen/Reader communication error.	Dock Pen, charge batteries, and retest with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.
Reader LCD displays "E52."	Pen not responding to Reader.	Dock Pen, charge batteries, and retest with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.
Reader LCD displays "E53."	Communication protocol failure between Pen and Reader.	Dock Pen, charge batteries, and retest with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.
Reader LCD displays "E54."	Reader and Pen software do not match size error.	Test with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.
Reader LCD displays "E55."	Reader and Pen firmware incompatible version error.	Test with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.
Reader LCD displays "E56."	Pen failed premeasurement relay check.	Test with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.
Reader LCD displays "E57."	Pen battery will not hold a charge.	Test with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.
Reader LCD displays "E58."	Measurement attempted with uncalibrated Pen.	Test with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.

OSMOLARITY SYSTEM ⊕ WARRANTY

The TearLab Reader and Pens ("Product") are warranted against defects in material and workmanship for 12 months from the date of delivery. The foregoing warranty is subject to the following conditions and exceptions:

Warranty excludes repair of failures resulting from mishandling or abuse. Warranty excludes consumable items such as Test Cards. Warranty does not apply to damage sustained in transit. Warranty service may only be performed by TearLab Corporation ("TearLab"), or its authorized representative. Warranty is void if the Product has been modified or repaired by anyone other than TearLab or its authorized representative. Warranty is nontransferable. Warranty is void if the serial number tag is removed or altered. If the Product fails to conform to the foregoing warranty, you may return the nonconforming Product during the 12-month warranty period accompanied by (a) a copy of the sales receipt of the Product (for the purposes of evidencing the applicable warranty period) and (b) a Return Material Authorization ("RMA") number for the defective Product obtained from TearLab prior to initiating the shipment of the defective Product to TearLab. Products returned without a sales receipt and valid RMA number shall be returned to you, with no further obligation by TearLab regarding the Product. If you return a Product in compliance with the foregoing requirements, TearLab shall repair or replace the Product as soon as reasonably practicable.

THE REPLACEMENT OF THE NONCONFORMING PRODUCTS BY TEARLAB AS PROVIDED ABOVE SHALL BE YOUR SOLE AND EXCLUSIVE REMEDY FOR BREACH OF THE FOREGOING WARRANTY.

OTHER THAN AS WARRANTED ABOVE, THE PRODUCT IS PROVIDED AS IS. TEARLAB MAKES NO OTHER WARRANTIES RELATING TO THE PRODUCT, EXPRESS OR IMPLIED, AND EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION, WARRANTIES OF NONINFRINGEMENT, FITNESS FOR A PARTICULAR PURPOSE, OR MERCHANTABILITY.

In the event you experience any difficulty with the TearLab Osmolarity System, contact your local sales representative or TearLab Customer Support.

OSMOLARITY SYSTEM ⊕ EMC AND SAFETY

SPECIFICATION	FREQUENCY RANGE
EN 55011: 2007, Group 1, Class "A" Conducted Emissions	0.15 MHz – 30.00 MHz
EN 55014-1: 2006 Disturbance (Click)	0.15 MHz – 30.00 MHz[1]
EN 55011: 2007, Group 1, Class "A" Radiated Emissions	30.00 MHz – 1000 MHz
EN 61000-3-2: 2000/A2: 2005 Power Line Harmonics	Up to the 40th Harmonic
EN 61000-3-3: 1995/A1: 2001/A2: 2005 Power Line Flicker	Less than or equal to 4% Maximum Relative Voltage Charge; Value of D (T) less than or equal to 3% for more than 200 ms

NOTE 1: No discontinuous disturbance (clicks) identified at this frequency range.

SPECIFICATION	MINIMUM TEST LEVEL REQUIRED PER EN 60601-1-2 FOR NON-LIFE SUPPORT EQUIPMENT	TEST LEVEL COMPLETED
IEC 61000-4-2: 1995/A1: 1998/A2: 2000 - Electrostatic Discharge Immunity	Air Discharge up to ± 8kV Contact Discharge up to ± 6 kV	Air Discharge up to ± 8kV Contact Discharge up to ± 6 kV
IEC 61000-4-3: 2006 - RF Radiated Fields Immunity	Radiation Field Strength of 3V/m From 80–6000 MHz (80% AM @ 1 kHz)	Radiation Field Strength of 3V/m From 80–6000 MHz (80% AM @ 1 kHz)
IEC 61000-4-4: 2004 + Corrigendum 1: 2006 - Electrical Fast Transient Immunity	Power line pulses of ± 2 kV direct; I/O line pulses of ± 1 kV	Power line pulses of ± 2 kV direct; I/O line pulses of ± 1 kV
IEC 61000-4-5: 2005 - Lightning Surge Immunity	Power line surge of ± 2 kV common, ± 1 kV differential mode	Power line surge of ± 2 kV common, ± 1 kV differential mode
IEC 61000-4-6: 2004/A2: 2006 - RF Common Mode Immunity	150 kHz–80 MHz at 3 Vrms 1 kHz 80% amplitude modulated	150 kHz–80 MHz at 3 Vrms 1 kHz 80% amplitude modulated
IEC 61000-4-8: 1993/A1: 2000 Power Frequency Magnetic Field Immunity	Helmholtz coil at 50 Hz and 60 Hz, to 3 amps (rms) per meter	Helmholtz coil at 50 Hz and 60 Hz, to 3 amps (rms) per meter
IEC 61000-4-11: 2004 - Voltage Dips and Short Interruptions	Voltage Dips of >95%, 30%, and 60%; interruptions of >95%	Voltage Dips of >95%, 30%, and 60%; interruptions of >95%

The TearLab Osmolarity System is intended for use in an electromagnetic environment with controlled HF disturbances. The user of the TearLab Osmolarity System can help to avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile telecommunication devices (transmitters) and the TearLab device — depending on the output power of the telecommunication devices as described below.

	SAFETY DISTANCE DEPENDING ON THE FREQUENCY IN m		
Rated maximum output power of transmitter W	150 kHz to 80 MHz d={ 3,5/V1 }√P	80 MHz to 800 MHz d={ 3,5/E1 }√P	800 MHz to 2,5 GHz d={ 7/E1 }√P
0,01	0.12	0.04	0.08
0,1	0.37	0.11	0.22
1	1.17	0.35	0.70
10	3.7	1.11	2.22
100	11.67	3.50	7.00

For transmitters with a maximum nominal power not mentioned above: To detect the recommended safety distance, use the equation in the corresponding column. P is the maximum nominal power of the transmitter in watt (W) according to the specifications of the transmitter manufacturer.

NOTE: These guidelines may not be applicable for all cases. The propagation of electromagnetic values is influenced by absorptions and reflections of buildings, objects, and people.

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GLOSSARY OF SYMBOLS			
	Date of manufacture		Use by date
	Manufacturer	SN	Serial number
IVD	*in vitro* diagnostic device	REF	Catalog number
	Consult Instructions for use	EC REP	Authorized representative for the European Union
CONTROL	Control		Type B applied part IEC 60601-1

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One or more of the following patents may apply: U.S. Patents 7,017,394; 7,051,569; 7,111,502; 7,129,717; 7,204,122.

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